NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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On:

The Impact of CMS Regulations and Programs on Small Health Care Providers

To:

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INTRODUCTION

Members of the Committee, thank you for allowing the National Association of Chain Drug Stores (NACDS) the opportunity to participate in today's hearing to discuss the impact of CMS regulations and programs on Medicaid and Medicare beneficiary access to retail pharmacies. NACDS represents approximately 200 companies operating retail pharmacies in virtually every community in the country. The size of those companies ranges greatly. NACDS represents national companies with thousands of retail pharmacies as well as local chains that operate as few as four pharmacies.

Regardless of their size, all NACDS members are deeply concerned about the following: (i) the impact of unfair Medicaid cuts for pharmacy services, (ii) program inefficiencies and unfair treatment of retail pharmacy under Medicare Part D, and (iii) threats posed by program requirements under the Medicare Part B Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) program, including competitive bidding. We outline below our concerns and suggestions for fair treatment of pharmacy under both the Medicaid and Medicare programs.

MEDICAID REIMBURSEMENT CUTS THREATEN ACCESS TO PHARMACY CARE FOR MEDICAID BENEFICIARIES

The Deficit Reduction Act of 2005 (DRA) required significant cuts to Medicaid pharmacy reimbursement for generic drugs. These cuts, as implemented by the Centers for Medicare and Medicaid Services (CMS), will result in pharmacies being reimbursed below the costs of acquiring many common generic drugs and cause upwards of 12,000 pharmacies to close nationwide.

The DRA and subsequent CMS regulations implementing the law set the maximum payment for generic drugs – known as the Federal Upper Limit (FUL) - using a calculation based on the lowest reported average manufacturer price (AMP), or the average price that manufacturers sell drugs to wholesalers for resale by retail pharmacies. The FUL places a cap on Medicaid reimbursement of the cost of generic drugs and does not include the cost of dispensing the drug. The AMP data on which generic drug FULs, and pharmacy reimbursement, are to be based will not include the markup that retail pharmacies normally pay to wholesalers. This is a significant change from previous practice, under which FULs were based on the lowest published list price (expressed as average wholesale price, AWP, or wholesale acquisition cost, WAC). In addition, FULs will be established when as few as two versions of a particular generic drug exist rather than three, as had previously been the case.

The DRA cuts to Medicaid reimbursement -- and the final rule to implement those cuts, place many retail pharmacies at risk of being forced to eliminate service to Medicaid recipients or close altogether. Many pharmacies that serve Medicaid patients will not survive the AMP cuts due to payments lower than their purchase price for generic drugs. Both the General Accountability Office and the HHS Office of Inspector General confirmed that the AMP system would reimburse pharmacies below their acquisition

costs for many common generic drugs. This could result in as many as 12,000 pharmacies going out of business, which represents about 20 percent of all pharmacies in the country according to expert testimony of Stephen Schondelmeyer of Prime Institute. That could devastate the prescription drug delivery system in this country, not just for Medicaid patients, but for millions of others and potentially increase other patient health care costs due to access limitations.

The final rule on AMP that CMS issued in July 2007 is unlawful because it exceeds statutory authority for calculating the reimbursement cap, or FULs, for generic drugs. The DRA defines AMP as "the average price paid to the manufacturer for a drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." However, the rule includes sales in that average price that do not belong in the calculation of AMP because they are not prices paid to manufacturers by wholesalers for drugs distributed to the retail class of trade. Improperly included sales to patients, physicians, surgical centers, dialysis centers, mental health centers, home health providers, home infusion providers, clinics, hospital outpatient pharmacies or a hospital affiliated entity, pharmacy benefit managers, mail order pharmacies, and sales at nominal price to "any entity" were included in the AMP rule as sales for drugs that are distributed to the retail pharmacy class of trade. In fact, not only are these sales for drugs that are never distributed to the retail class of trade, many of these purchasing entities are able to purchase drugs at a lower cost than retail pharmacy, which would result in a lower AMP used to calculate a lower reimbursement cap on generic drugs for Medicaid pharmacies. In addition, the AMP rule would publish the resulting flawed AMP data on a public website which could further harm retail pharmacies, not only affecting Medicaid reimbursement to pharmacies but reimbursement from other third party payers as well.

The AMP rule also misses the mark in that it fails to provide a thorough analysis of the economic impact that the rule would have on small pharmacy businesses, as required under the Regulatory Flexibility Act. A rule that would so drastically cut reimbursement to Medicaid pharmacies without a thorough economic impact analysis is irresponsible at best. With so much at stake - Medicaid beneficiaries' access to prescription medicine and pharmacy services and the livelihood of the community pharmacists dedicated to keeping them well - more emphasis should have been placed on the impact of this rule before it was published.

In December 2007, a federal court issued a temporary injunction to halt CMS' implementation of the Agency's final rule as result of a lawsuit filed by NACDS and the National Community Pharmacists Association (NCPA). The court order prohibits CMS from using the AMP data to calculate FULs pending resolution of the lawsuit. It also prohibits the publishing of AMP data by CMS or the distribution of the data to the States.

Although the preliminary injunction granted a delay in the implementation of this devastating rule, regardless of the decisions of the court, the DRA statutory cuts will eventually be implemented. Retail pharmacy and Medicaid beneficiaries need Congress to intervene to prevent these cuts to pharmacy reimbursement that remain a threat to patient access to drugs. A long-term remedy would require an act of Congress to change

the statute upon which CMS has based the AMP rule. Legislation to make the needed changes to protect access to prescription drugs and services and provide for fair reimbursement to pharmacies has to happen this year. We urge Congress to act quickly to enact legislation to revise the DRA provisions that threaten patient access to drugs and to protect the vital role that pharmacies play in our nation's health care system.

SUGGESTIONS TO RESOLVE PROGRAM INEFFICIENCIES AND UNFAIR TREATMENT OF RETAIL PHARMACIES IN MEDICARE PART D

NACDS members are the primary providers of pharmacy services to beneficiaries under the Medicare Part D program. While the Medicare prescription drug program has helped millions of Americans obtain their medications, the program is still plagued by some design and administrative problems that often create access difficulties for beneficiaries. First, beneficiaries are often unable to obtain their medications in time due to the enrollment lag that occurs after they enroll or switch into their new drug plans. Second, Medicare beneficiaries are often denied access to extended supplies of medications from their local community pharmacies because CMS has failed to implement this provision consistent with the Medicare statute and Congressional intent. Finally, Part D plans do not provide pharmacies with adequate disclosure of terms for reimbursement when pharmacies sign network pharmacy contracts. We ask the Committee to consider our recommendations to make the Medicare Part D program more successful for patients.

Establish a rolling-enrollment period for more effective Medicare Part D.

Like other parts of Medicare, seniors generally become eligible for the prescription drug benefit under Medicare Part D when they reach the age of 65. Others who were of requisite age but did not elect Part D coverage in the previous year(s) may decide to join a Part D plan at any time in the current year. As a result, many seniors become eligible for Medicare Part D on a daily basis and accordingly sign up to enroll in a Medicare Part D plan. Once beneficiaries apply to enroll in a plan, their applications must be processed by the plans, sent to CMS for confirmation, entered into the Part D plans' systems and then entered into the pharmacy systems before the beneficiaries can obtain their prescription drugs.

When a Medicaid recipient becomes eligible for Medicare, they are assigned to a Part D Plan but they are not required to remain in the plan. These "dual-eligible" beneficiaries (those eligible for Medicare and Medicaid) may switch plans every month. As a result, each time a dual-eligible beneficiary switches to a new plan, the same application process is repeated and must be completed before their benefits can begin.

Further, many beneficiaries enroll or switch into new plans during the annual coordinated election period, which occurs between November 15 and December 31 of each year. Again, their applications must be processed by the plans, sent to CMS for confirmation and entered into the plans' and pharmacies' systems.

For all of these beneficiaries, Part D benefits generally begin on the first day of the month following the month in which they enroll in or switch to their new plan. Under the current system, beneficiaries can technically expect to access their Part D benefit on the first day of the month, no matter how late in the previous month they joined or switched to a new plan. In reality, however, CMS and the plan cannot process the application, confirm eligibility, and provide information to the True Out-of-Pocket (TrOOP) facilitators in time for the benefits to become available on the first of the month if a beneficiary enrolls in or switches into a new plan on the last few days of the previous month. This lag in enrollment causes tremendous frustrations for providers and places beneficiaries in unnecessary danger of not being able to obtain their medications.

As patients visit their pharmacy, many will find that their enrollment information is not yet available on the pharmacy's system and will be unable to obtain their drugs. In such cases, pharmacies spend significant amounts of resources and time tracking eligibility, including calling plans' help desks to determine whether the beneficiary is eligible. If the beneficiary does not know what plan they signed up for (which is a common occurrence with dual-eligibles who have been assigned a plan) and a subsequent query on the pharmacy's computer system does not provide some indicia of coverage, the pharmacy is placed in an even more unworkable situation and faced with a tough decision – it can either fill the script and absorb the cost or turn the patient away.[1] Both situations are unacceptable and dangerous for patients.

The crux of the problem is that there is not enough time under the current system for processing to occur within a few days such that beneficiaries who sign up late in the month can obtain their medications at the beginning of the next month. Processing of Medicare enrollment can take two weeks or more in some cases. Often, plans do not forward necessary information about an applicant to CMS in a timely manner, which compounds the problem. While we commend CMS for reducing the overall time it takes to process Part D enrollment applications, the problem continues for late enrollees or those who switch plans.

Recommendation: Congress should establish a minimum amount of time between the time when a beneficiary enrolls in a Part D plan and the time they can start using their plan at the pharmacy to obtain their medications. Such a "rolling-enrollment" system would assure that important beneficiary and billing information are processed by both CMS and plans and entered into the pharmacy's computer system so patients can obtain their medications on time. Rather than provide false expectation that a beneficiary can obtain benefits on the first of the month no matter how late they enroll, this proposal will encourage beneficiaries to sign up early for their Part D benefits. CMS should also

[1] While CMS does allow pharmacies to enroll certain dual-eligible or low income subsidy individuals through the point-of-sale facilitated enrollment process, the system requires pharmacies to verify eligibility by examining documents provided by the beneficiaries. All too often, beneficiaries are unable to provide such documents as Medicaid ID card, Medicaid award letter, low income notice and others for pharmacies to verify coverage.

require plans to forward beneficiaries' applications to CMS for confirmation of coverage in a timely manner. These improvements will help ensure that beneficiaries can obtain their medications on time without any interruption to their medication therapy and will reduce frustration and stress for both pharmacists and beneficiaries.

Allow beneficiaries to obtain extended supply of drugs from any community retail pharmacy of their choice.

When beneficiaries obtain their medications from community retail pharmacies, they receive tremendous benefits that are not found anywhere else. For example, patients benefit from immediate access to counseling from a state-licensed pharmacist when they obtain their medications from retail pharmacies. During their face-to-face professional counseling, pharmacists can address not only any special needs concerning the prescribed medication but identify other health conditions and issues early so as to improve the health outcomes of their patients. As pharmacists often have long-term relationships with their patients, they are aware of the patients' unique conditions and needs and can address those concerns appropriately. These types of benefits are not available when patients order their medications through the mail.

Congress recognized these unique benefits when it passed the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003.[2] The MMA requires that beneficiaries have access to pharmacy services from any retail community pharmacy of their choice. Congress was concerned that Part D plans may attempt to push patients to utilize mail-order facilities for services, including access to extended supply of drugs.[3] Therefore, the MMA specifically stated that beneficiaries shall be able to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail-order pharmacy), with any differential in charge paid by such enrollees. This provision provided Medicare Part D beneficiaries with an option as to how they wish to receive their pharmacy services.

Despite the clear language in the MMA requiring a level playing field between retail and mail-order pharmacies, CMS' implementation of this important provision and its guidance documents on how plans should follow the level playing field requirement are inconsistent with statute and Congressional intent. As a result, plans are effectively denying patients' access to an extended supply of drugs, i.e. a 90-day supply, from their community pharmacies.

CMS' guidance indicates that Part D plans are "expected" to allow a retail pharmacy to offer an extended supply of drugs to any plan beneficiary at the same price,

[2] 149 CONG. REC. S15743 (Nov. 24, 2003) [hereinafter *Hearing*] (during floor debate Sen. Enzi noting that, seniors trust their local pharmacists and should be allowed to keep those relationships in place).
[3] *Id.* (Sen. Enzi stated that, the level playing field provision was intended to prohibit plans from "implementing restrictions that would steer consumers to mail-order pharmacies." Chairman Grassley "expect[ed] that the Secretary of Health and Human Services would disapprove of any plan that would impose a differential charge that was intended primarily to steer Medicare beneficiaries to mail-order pharmacies versus retail pharmacies.")

reimbursement rate (including dispensing fee, if any) and cost sharing as the plan's mail-order pharmacy. CMS' guidance then goes on to state that the plan "may" allow retail pharmacies to dispense an extended supply of drugs for a higher contracted rate than the mail-order rate (called the alternative retail/mail-order rate). However, any difference in charge between the two rates would be paid by the beneficiary (or the pharmacy, as long as it was cost neutral to the plan). This interpretation by CMS erroneously suggests that plans have the discretion as to whether they allow pharmacies to dispense a 90-day supply at the higher non-mail-order rate even when a beneficiary is willing to pay the difference.

CMS' interpretation is contrary to the intent of the MMA, which requires that the beneficiaries have a choice of obtaining their covered Part D drugs either through mail or through their retail pharmacy, paying any difference in charge to obtain the drugs through the retail pharmacy. This presumes the pharmacy is willing to participate at the alternative rate and plans are required to offer this option to pharmacies. CMS' own regulation also states that the plan *must* permit its Part D enrollees to receive benefits, such as a 90-day supply, at any of its network pharmacies that are retail pharmacies.[4] Accordingly, plans do not have the discretion to exclude pharmacies from dispensing a 90-day supply if they do not accept the mail-order rate.

Nonetheless, based on CMS' guidance, plans often deny pharmacies the ability to dispense extended supply of drugs if they do not accept the mail-order rate. These plans feel that they are only required to offer the mail-order rate to retail pharmacies but not the alternative retail/mail-order rate. If retail pharmacies do not accept the mail-order rate, then the plan "may" offer the alternative rate, but the plans indicate that they do not believe that they are obligated to do so.

In some cases, however, plans may allow retail pharmacies to dispense an extended supply of drugs for a higher contracted rate than the mail-order rate, but require patients to pay much higher co-pays for a 90-day supply at a retail pharmacy than the co-pays required for mail-order. Often, these co-pay differences are designed to discourage the use of retail pharmacy as they do not reflect the cost to the plan of allowing the retail pharmacy to dispense a 90-day supply. These practices are contrary to Congressional intent and unjustifiably push patients to mail-order.[5]

Often, Part D plans make mail-order pharmacies their preferred pharmacy for extended supply of drugs. A retail pharmacy is not allowed to participate as a preferred pharmacy unless it will also provide an extended supply of drugs through mail-order. Even when a retail pharmacy may be willing to accept the preferred mail-order pharmacy's rate, the plan will require the retail pharmacy to participate at the non-preferred rate, which usually requires patients to pay higher co-pays and thereby encourages the plan's mail-

[4] 42 C.F.R § 423.120 (2008) (emphasis added).
[5] *Hearing, supra* note 2, at S15743 (Sen. Enzi and Chairman Grassley both remarked that differences in charge between mail order and retail be reasonable. Sen. Enzi further noting that, he would be concerned if differences in charges were used to steer patients to mail order).

order business. These policies deny fair choice to seniors and ultimately drive prescriptions to mail-order.

Recommendation: Absent a clear direction requiring CMS to follow Congressional intent to allow any community retail pharmacy the ability to dispense extended supply of drugs, plans will continue to rely on CMS' misinterpretation of the level playing field provision as a license to deny patients a choice in their own health care. We urge Congress to take strong action to clarify that plans must provide beneficiaries with access to an extended days supply at any community retail pharmacy of their choice.

Require disclosure of generic drug reimbursement rate and update of reimbursement benchmarks.

Pharmacies are required to sign network pharmacy contracts with Medicare Part D plans to dispense drugs to Part D beneficiaries in their network. Often, these contracts are lacking in critical reimbursement information that should be provided to pharmacies at the time of the contract offer. Specifically, Part D plans' network contracts with pharmacies often reference Maximum Allowable Cost (MAC) lists or prices for reimbursement of generic drugs. The MAC is the maximum amount of reimbursement a network pharmacy could receive for dispensing generic drugs that are listed on the MAC list. While plans' contracts with pharmacies reference MAC lists or prices, pharmacies are not provided such list or pricing during contract negotiations, thereby requiring pharmacies to sign network pharmacy contracts without adequate disclosure of the reimbursement they will receive from plans for the generic drugs they dispense. Additionally, plans retain the right to change the MAC price at "their discretion" without notification.

Some Part D plans also do not regularly update their pricing benchmarks (e.g., Average Wholesale Price, AWP, or Wholesale Acquisition Cost, WAC) to appropriately account for pharmacies' increased costs of purchasing drugs. These benchmarks are provided by an independent third party on a frequent basis (in some cases, daily) to reflect the prices of these drugs on the market. Even though current, updated benchmarks are available, plans do not update their reimbursement to pharmacies to accurately reflect the prices pharmacies pay to purchase these drugs. The reimbursements pharmacies receive are often based on outdated pricing databases, which results in pharmacies being underpaid for the prescriptions they dispense and creates a severe cash-flow problem for pharmacies. Given that pharmacies are expected to pay current "real-time" prices to manufacturers and wholesalers for their drugs, reimbursement by Part D plans to pharmacies should also be based on up-to-date pricing information.

Recommendation: We urge Congress to create a fair contracting environment under Part D by requiring plans to disclose generic drug reimbursement rates at the time of contract. Plans should also be required to update their reimbursement to pharmacies reflecting the date of the pricing change as reimbursement benchmarks are updated. Absent a legislative requirement for fairness and upfront disclosure during Part D contract process, plans will continue to deprive pharmacies of important reimbursement terms and updates.

Ensuring that pharmacies are reimbursed appropriately is critical in ensuring their continued ability to provide services under Medicare Part D.

THREATS POSED BY NEW REQUIREMENTS UNDER THE MEDICARE PART B DMEPOS PROGRAM, INCLUDING COMPETITIVE BIDDING

Medicare patients obtain coverage for DMEPOS through the Medicare Part B program. Durable medical equipment includes such items as diabetic testing supplies and monitors, walkers, hospital beds, wheel chairs, and oxygen equipment and supplies. Many Medicare beneficiaries obtain these supplies from their local pharmacies. In fact, a recent study conducted by HealthPolicy R&D found that nearly two-thirds of older diabetic patients obtain their diabetes test strips from their retail-based community pharmacies.[6] Retail pharmacies are the largest providers of DMEPOS services to Medicare patients and are in a unique position to assist patients with their care and treatment and to monitor disease trends and therapy outcomes. In many cases, a pharmacist is the most readily accessible health care provider in the community for the Medicare beneficiary. One-on-one patient-pharmacist consultations can often provide the first opportunity to identify chronic illnesses and changes in patient conditions, and these consultations often result in early detection, referral, and treatment. In addition to helping to preserve the patient's health, early detection and treatment provides tremendous savings for the Medicare program. For many of these patients, the pharmacist serves as a gatekeeper assisting them and their caregivers in their health care management needs. Continued participation of community retail pharmacies in serving Medicare patients should therefore be an important consideration in the Medicare program.

Some aspects of the DMEPOS program, including accreditation, the competitive acquisition program and the surety bond rule proposed by CMS will prevent pharmacies from effectively serving their Medicare patients. CMS' requirement for DMEPOS supplier accreditation creates significant administrative and financial burdens for small pharmacies. Further, any expansion of the competitive acquisition (hereafter "competitive bidding") program for DMEPOS to include diabetes supplies sold at retail or CMS' plan to establish national or regional competitive bidding areas for mail-order diabetes testing supplies could limit participation by small pharmacies and reduce diabetic patients' access to life-saving supplies and services. Finally, CMS' proposal to require a $65,000 surety bond from state-licensed pharmacies will present tremendous cost to pharmacies without any enhancement to the integrity of the Medicare program. We offer our thoughts to help the Committee address these issues to help ensure that beneficiaries have access to high quality products and services from their pharmacies.

[6] HealthPolicy R&D, *Medicare's New Competitive Acquisition Program for Durable Medical Equipment: Policy Considerations Involving Beneficiaries with Diabetes, Community-Based Retail Pharmacies and Blood Glucose Monitoring*, Washington, DC, January 2006.

State-licensed pharmacies should be exempt from the accreditation requirement.

The MMA requires DMEPOS suppliers to be accredited to sell covered items to Medicare patients and to participate in the competitive bidding program.[7] The goal of this requirement is to reduce fraud, waste and abuse in the Medicare program. While we agree with CMS on the importance of eliminating fraud, waste and abuse from the Medicare program, we do not believe that requiring accreditation of state-licensed pharmacies will accomplish this goal. CMS has at its disposal a variety of tools to ensure provider integrity in the Medicare program, which CMS could pursue instead of the onerous accreditation requirement. Accreditation of state-licensed pharmacies is an unnecessary requirement that could threaten patients' access to DMEPOS supplies from their most accessible health care provider.

We are concerned that requiring accreditation of pharmacies could result in reducing the number of pharmacies that are available to supply DMEPOS to Medicare beneficiaries. The costs associated with the accreditation process, which can amount to several thousand dollars and hundreds of man-hours for each pharmacy, creates a tremendous financial barrier for pharmacies that provide DMEPOS items to their patients. Pharmacies already struggle to minimize operational expenses to remain competitive in the marketplace, and are skeptical of the accreditation process because even if they undergo the accreditation process, they have no guarantees that they will ultimately be allowed to participate in the DMEPOS program. Combine this requirement with the proposed reimbursement cuts in Medicaid and other state programs and pharmacies are forced to closely examine their expenses.

Accreditation of state-licensed pharmacies is unnecessary due to the comprehensive licensure requirements for pharmacies and pharmacists. Pharmacies are licensed by the board of pharmacy of their respective states to provide services to patients. As part of their licensing process, pharmacies submit to rigorous requirements for their operations and compliance with federal and state laws. Further, state pharmacy laws mandate that each pharmacy have a designated pharmacist who is responsible and accountable for the operation of that pharmacy in compliance with appropriate laws and regulation. Today's pharmacists are highly educated, licensed experts in the use of medications and medical devices who advise patients and health care providers. These pharmacists are ideally situated to provide Medicare patients using diabetes supplies and other DME items with appropriate counseling and information on the proper use of these items. These qualifications clearly distinguish pharmacies and pharmacists from other unlicensed and unregulated suppliers.

While we believe that accreditation should not be required of pharmacies, we understand the mandate on CMS to implement the accreditation requirement under the MMA.

[7] CMS has announced that *all* suppliers must be accredited by September 30, 2009 to maintain billing privileges under Medicare Part B. Those participating in the competitive bidding program are required to be accredited even sooner.

Nevertheless, CMS' recent implementation of the accreditation requirement through different deadline dates for suppliers with less than 25 locations has resulted in inequitable and unfair treatment of smaller suppliers. On December 19, 2007, CMS announced that existing DMEPOS suppliers enrolled in the Medicare program must obtain and submit an approved accreditation to the National Supplier Clearinghouse (NSC) by September 30, 2009. New DMEPOS suppliers who are enrolled for the first time before March 1, 2008 must obtain and submit an approved accreditation to the NSC by January 1, 2009. However, new DMEPOS suppliers with less than 25 locations submitting an enrollment application to the NSC on or after March 1, 2008 are required to be accredited prior to submitting their Medicare enrollment application.

The accelerated accreditation requirement for existing chain suppliers with less than 25 locations that open new stores on or after March 1, 2008 is arbitrary and unfair. The tiered accreditation deadline based on number of locations creates differential treatment for suppliers. Because CMS has conditioned the Medicare supplier numbers for new locations of an existing supplier on accreditation of the entire chain, the accelerated accreditation deadline also creates a back-log for accrediting organizations. Although CMS provided additional time, until September 30, 2009, for new and existing locations of chain suppliers that have 25 or more enrolled locations to become accredited, CMS retained the unfair tiered approach for suppliers that do not meet the 25 location threshold. While we appreciate the extension provided to suppliers with 25 or more locations, CMS should treat all *existing* chain suppliers with the same degree of fairness and create a single accreditation deadline.

Recommendation: To reduce the difficulties posed by the accreditation requirement on pharmacy providers and to ensure patients' continued access to DMEPOS items, we urge Congress to specifically exempt state-licensed pharmacies from the accreditation requirement. We also urge Congress to ensure careful oversight of CMS' administration of this and other elements of the DMEPOS program to ensure fair treatment of small providers.

Diabetes testing supplies sold at retail pharmacies should not be subject to competitive bidding.

The DMEPOS competitive bidding program was mandated by the MMA. The program is currently limited to 10 metropolitan statistical areas (MSAs) during the initial round and includes bidding for ten categories of medical equipment and supplies. CMS has also recently announced the second round of the program, which expands the program to an additional 70 MSAs. While CMS has excluded diabetes supplies sold at retail from both rounds of competitive bidding, we urge Congress to require CMS to continue this exemption in the future.

Currently, Medicare beneficiaries can obtain their diabetic glucose monitors and testing supplies from any retail pharmacy that participates in the Medicare program, allowing beneficiaries to obtain all of their covered equipment, supplies, and prescription drugs for managing their diabetes from the same qualified pharmacist. As mentioned earlier, the

majority of older diabetic patients rely on their retail pharmacies for their diabetic supplies. Evidence shows that pharmacist-based programs can result in clinically significant improvements in health outcomes for diabetic patients. Through programs such as the "Asheville Project," the pharmacy setting has been shown to provide a successful platform for initiatives to improve adherence to testing and treatment regimens for patients with diabetes.[8] Other private and public health care programs have also placed the pharmacist in a central role in the management of diabetes and other chronic diseases. It would be ill-advised to risk disrupting these pharmacist-patient relationships while further experience is being gained in the effectiveness of community-based pharmacies in promoting adherence to blood glucose treatment and monitoring regimens.

Unlike other DME supplies, CMS did not evaluate the effects of competitive bidding of diabetes supplies during the competitive bidding demonstration projects. Thus, expansion of the competitive bidding program to diabetes supplies sold at retail pharmacies will create significant confusion and frustration to diabetic patients and their providers. At a time when Medicare is attempting to move away from fragmented care, competitive bidding is likely to interfere with patient access and could adversely affect diabetes management.

Further, the study conducted by HealthPolicy R&D examined issues related to competitive bidding of diabetic products and associated services under Medicare Part B and noted the following:

- Costs to the Medicare program will increase if access to the full range of monitoring options is lost or if the frequent in-person counseling by retail pharmacists is disrupted.
- The complexity of using glucose monitors, particularly for an elderly beneficiary, is a major concern. Pharmacists play an important role in helping beneficiaries select the optimal monitors and in the correct use of such monitors, both in terms of initial instruction and subsequent reinforcement of that instruction over time. Much of the professional support originates from the ongoing relationship between beneficiaries and pharmacists.
- CMS excluded blood glucose monitors and supplies from the DME competitive bidding demonstration project, due, in part, to concerns regarding the complexity of matching glucose monitors with the appropriate testing supplies.
- The competitive bidding program could operate contrary to Medicare's current and future initiatives that are designed to promote adherence to blood glucose regimens and reduce overall costs in managing diabetes.

[8] Pharmacy Times, *The Ashville Project: A Special Report* (October, 1998), *available at* http://www.pharmacytimes.com/files/articlefiles/TheAshevilleProject.pdf (last accessed May 12, 2008).

CMS should not create national or regional competitive bidding areas for mail-order diabetes supplies.

Although CMS excluded diabetes supplies sold at retail from the first and second rounds of competitive bidding and diabetes supplies sold anywhere from the second round, CMS continues to maintain that it will soon create a national or regional mail-order program for diabetes supplies.

CMS' decision to expand the mail-order program for diabetes products would not be supported by any evidence that mail-order program would ensure quality products and services or guarantees as to patients' access to life-saving diabetes products. As CMS' primary motivation appears to be financial savings, it is quite likely that a winning mail-order supplier may limit access to high quality products and eliminate patients' choice in their diabetes care in order to cover reduced reimbursement under the mail-order competitive bidding program.

Further, CMS has not engaged in any study or evaluation of the impact of a mail-order diabetes program on patients' health outcomes and overall increase in cost to the Medicare program from patients' failure to abide to their prescribed testing regimen. As mentioned earlier, proper match between diabetes test strips and monitor is critical to optimal diabetes management. If patients are unable to access proper diabetes test products or find it difficult to manage their diabetes with low-quality products, they are much more likely to stray from proper testing regimen or stop testing entirely. These behaviors are likely with a mail-order program, which will undoubtedly harm patients and increase Medicare spending.

Like many other chronic diseases, diabetes has a disproportionate impact on minority and low income patients. These populations are less likely to be able to navigate a competitively bid mail-order market for their diabetes products. As retail pharmacies and providers are selectively forced out of diabetes supplies business through the expansion of the mail-order program, minority and low income populations will find it increasingly difficult to access these products. Expansion of the mail-order program will effectively compel these vulnerable populations to go without proper diabetes management.

As previously stated, the majority of older patients prefer to obtain DME supplies for conditions such as diabetes from their local pharmacist with whom they have an ongoing relationship. The presence of a licensed pharmacist at their community retail pharmacy gives patients the opportunity to discuss the best glucose test monitors for their individual needs and the proper matching of the test strips to the glucose test monitors. This individualized attention is critical to helping increase patient compliance with therapy regimen and improving health outcomes for diabetic patients. The benefit of such interaction should not be taken lightly as it provides a valuable patient care forum for early awareness and treatment of diseases, and translates into substantial savings for the Medicare program. Expansion of the mail-order diabetes program will make it more difficult for Medicare patients to gain access to the community pharmacist they trust creating a likelihood for miscommunications and misunderstandings and eroding the

benefits of the pharmacist-patient relationship that has been proven to improve health outcomes and reduce overall health care spending.

Finally, we also urge Congress to be cautious of CMS' implementation of the first round of competitive bidding, which included bidding for mail-order diabetes supplies. With less than two months remaining before first round mail-order diabetes supplies contracts go into effect in the 10 MSAs, CMS has not embarked upon an effective patient outreach program. As the first round becomes effective on July 1, 2008, patients are likely to be confused about where they can obtain their DMEPOS products and services. In particular, diabetes patients in the 10 MSAs may mistakenly believe that they are required to utilize a mail-order facility for their diabetes supplies. CMS should be required to clearly state on any beneficiary communication material that patients in the 10 MSAs may continue to utilize their local pharmacies for their diabetes test supplies. As mentioned earlier, interaction with licensed pharmacists at retail pharmacies provides benefits that are not achievable when patients receive their diabetes products through mail-order. Congress should require CMS to work with the retail pharmacy community to develop proper communication materials to ensure that patients are not steered away from retail pharmacies, depriving them of professional counseling by pharmacists.

State-licensed retail pharmacies should be exempt from CMS' proposed surety bond rule.

During the midst of competitive bidding program implementation, CMS also proposed to require a $65,000 surety bond from all Medicare DMEPOS suppliers. As if the costs associated with accreditation and bidding did not create enough disincentives for small suppliers, CMS' proposal to require a surety bond is likely to keep many interested suppliers from participating in the DMEPOS program.

In its proposal, CMS estimated that annual administrative costs related to the surety bond would be $2000.[9] For many DMEPOS suppliers, the administrative fees required in obtaining the surety bond could be prohibitive as such fees may not be recouped even through their total annual Medicare billing. Ultimately, small DMEPOS suppliers, particularly those serving rural and underserved areas, may be unable to cope with the recurring and rising administrative costs in providing DMEPOS services and may be forced to turn away Medicare beneficiaries.

According to CMS' own calculation, up to 15,000 DMEPOS suppliers currently enrolled in Medicare (22 percent of whom are in rural areas) could cease providing items to Medicare beneficiaries as a result of the surety bond.[10] CMS envisions that, "most, if not all, of the Medicare business conducted by these DMEPOS suppliers would be assumed by other DMEPOS suppliers remaining in the program (for example, by mail-order or via

[9] Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 72 Fed. Reg. 42007 (August 1, 2007).
[10] *Id* at 42008.

the World Wide Web)."[11] Clearly, CMS indicated that this proposed rule will result in even fewer small pharmacies participating in the Medicare DMEPOS program. As a result, patients could face tremendous difficulties in obtaining their necessary DMEPOS items and services.

CONCLUSION

NACDS appreciates the opportunity to testify today and share our perspectives about current CMS regulations and policies affecting small health care providers and their patients. We look forward to working with Members of this Committee and Congress to address these harmful policies to ensure that Medicare and Medicaid beneficiaries' health is not placed in jeopardy.

[11] *Id.*